AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION,
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION *This document relates to* CLARA FORD, Individually and as Administrator of the Estate of GLADYS TURNER, Deceased, Plaintiff, vs. PFIZER, INC., PHARMACIA CORPORATION, G.D. SEARLE & CO., and MONSANTO COMPANY, Defendants.	MDL Docket No. 1699 CASE NO. 3:08-cv-1019-CRB **PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC'S ANSWER TO COMPLAINT** **JURY DEMAND ENDORSED HEREIN**

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a/ Monsanto Company[1]) ("Pharmacia"), and G.D. Searle LLC (improperly captioned in Plaintiff's Complaint as "G.D. Searle & Co.") ("Searle"), (collectively "Defendants") and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Decedent was prescribed or used Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Decedent was prescribed and used Celebrex®.

II.

ANSWER

Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint, Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny that Plaintiff is entitled to any relief or damages. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Parties

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and whether Plaintiff is the Administrator of Decedent's Estate, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants state that this paragraph of the Complaint contains legal contentions to

[1] Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex®. Given that Plaintiff alleges in the Complaint that Monsanto Company was involved in distributing Celebrex®, *see* PLAINTIFF'S COMPLAINT at Section II(C), Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

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275 Battery Street, Suite 2000
San Francisco, CA 94111

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275 Battery Street, Suite 2000
San Francisco, CA 94111

which no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether the named individuals are Decedent's statutory beneficiaries-at-law, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

II(A) Answering the paragraph A of Section II of the Complaint, Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

II(B) Answering the paragraph B of Section II of the Complaint, Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia is registered to do business in the State of Mississippi. Defendants admit that Pharmacia may be served through its registered agent. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

II(C) Answering the paragraph C of Section II of the Complaint, Defendants admit that in

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1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever manufactured, marketed, sold, or distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint. Defendants state that the response to this paragraph of the Complaint regarding Monsanto is incorporated by reference into Defendants' responses to each and every paragraph of the Complaint referring to Monsanto and/or Defendants.

II(D) Answering the paragraph D of Section II of the Complaint, Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Pfizer is registered to do business in the State of Mississippi. Defendants admit that Pfizer may be served through its registered agent. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction

4. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims that the amount in controversy meets

jurisdictional limits. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pfizer, Pharmacia, and Searle are registered to do and do business in the State of Mississippi. Defendants admit that they may be served through their registered agent. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Allegation Regarding Venue

6. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy and the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pfizer, Pharmacia, and Searle are registered to do and do business in the State of Mississippi. Defendants admit that Plaintiff claims that the amount in controversy meets jurisdictional limits. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

7. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time,

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275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

8. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

9. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

10. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

11. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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275 Battery Street, Suite 2000
San Francisco, CA 94111

Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

12. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

15. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

17. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

19. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

20. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

21. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

the Complaint.

22. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

24. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

25. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

26. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27. Defendants state that Celebrex® was and is safe and effective when used in accordance

with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® was unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

29. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

30. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

31. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

32. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex® and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be

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275 Battery Street, Suite 2000
San Francisco, CA 94111

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275 Battery Street, Suite 2000
San Francisco, CA 94111

prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

33. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Proximate Cause and Damages

34. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Punitive Damages

35. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 35 of the Complaint, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

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275 Battery Street, Suite 2000
San Francisco, CA 94111

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the

applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff and Decedent were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff or Decedent were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff or Decedent.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Decedent's

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treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff and Decedent was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff's and Decedent's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiff and Decedent knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by

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the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f

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to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of California and Mississippi, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff and Decedent failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

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San Francisco, CA 94111

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275 Battery Street, Suite 2000
San Francisco, CA 94111

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of California and Mississippi. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff or Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff or Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks

constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff or Decedent has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

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Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's and Decedent's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff and Decedent, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff or Decedent.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff and Decedent did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff and Decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff and Decedent.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiff and Decedent were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Plaintiff's damages, if any, are limited by the failure to mitigate by Plaintiff and Decedent.

Fifty-ninth Defense

59. Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiff or Decedent with any other person or entity.

Sixtieth Defense

60. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in Plaintiff's Complaint.

Sixty-first Defense

61. To the extent that Plaintiff relies upon any theory of breach of warranty, Plaintiff's claims are barred because Defendants did not make or breach any express or implied warranties, Plaintiff and Decedent failed to give reasonable notice to Defendants of any alleged breach or breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

Sixty-second Defense

62. Any verdict or judgment rendered against Defendants must be reduced under the laws of

the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiff or Decedent, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiff and Decedent may have settled their claims for alleged injuries and damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiff or Decedent and any such parties.

Sixty-third Defense

63. Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damage awards which arise under the United States Constitution and decisions of the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi Constitution, statutes, and decisions of Mississippi courts.

Sixty-fourth Defense

64. Defendants assert that Plaintiff's claim for punitive damages is governed and limited by Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the same.

Sixty-fifth Defense

65. Celebrex® and the Defendants' actions conformed to the state of the art medical an scientific knowledge at all times relevant to this lawsuit and Celebrex® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

Sixty-sixth Defense

66. Defendants satisfied their duty to warn under the learned intermediary doctrine and Plaintiff's claims are therefore barred.

Sixty-seventh Defense

67. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Sixty-eighth Defense

68. Plaintiff failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to Defendants in any possible future litigation.

Sixty-ninth Defense

69. Any judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to ward, are unconstitutional in that, among other things, they are void for vagueness and undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

Seventieth Defense

70. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any award of punitive damages is barred.

Seventy-first Defense

71. Plaintiff's claims are barred in whole or in part because Plaintiff lacks standing to bring such claims.

Seventy-second Defense

72. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff takes nothing from Defendants by reason of the Complaint;

2. That the Complaint be dismissed;

3. That Defendants be awarded their costs for this lawsuit;

4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's and

Decedent's alleged injuries, losses or damages is attributable to each person;

5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's and Decedent's injuries and damages; and

6. That Defendants have such other and further relief as the Court deems appropriate.

March 26, 2008

GORDON & REES LLP

By: :_____/s/_____
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

March 26, 2008

TUCKER ELLIS & WEST LLP

By: :_____/s/_____
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants PFIZER INC, PHARMACIA CORPORATION, and G.D. SEARLE LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

March 26, 2008

GORDON & REES LLP

By: :_____/s/_____
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

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TUCKER ELLIS & WEST LLP

By:_____/s/_____
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants
PFIZER INC, PHARMACIA CORPORATION, and G.D. SEARLE LLC